K003071

510(k) SUMMARY DEC 1 3 2000

In response to the requirements addressed by the Safe Medical Devices Act (SMDA) of 1990, a summary follows with the safety and effectiveness information upon which the substantial equivalence determination is based.

SUMMARY OF SAFETY AND EFFECTIVENESS FOR GLITTEREYES™ Soft (hydrophilic) Contact Lenses

1. **Submitter Information**

CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097
Contact Person: Terrina Wilder
Telephone No. 678-415-3809

2. **Device Name**

Classification Name: Soft (hydrophilic) Contact Lens
Proprietary Name: GLITTEREYES™ Soft (hydrophilic) Contact Lens, K003071

3. **Predicate Device**

ILLUSIONS® Soft (hydrophilic) Contact Lens (PMA #810005/S25)

4. **Description of the Device**

GLITTEREYES™ (tefilcon) Soft Contact Lenses are intended for use on the human eye to correct vision and to alter the apparent color of the eye. The lenses may be worn on a daily wear basis. When placed on the cornea, the lenses act as a refracting medium to focus light rays on the retina.

GLITTEREYES™ soft contact lenses are made by encapsulating glitter pigment in an iris pattern between two layers of tefilcon polymer similar to the ILLUSIONS® lenses. The green, gold, violet, blue, and red glitter pigments consists of calcium sodium borosilicate and titanium dioxide and a MP-24 Karat Gold pigment which consist of mica, titanium dioxide, and iron oxide. This pigmented region of the GLITTEREYES™ lens has an iris pattern diameter of approximately 12.5mm with a central pupil of approximately 5.3mm.

5. **Indications for Use**

GLITTEREYES™ (tefilcon) soft (hydrophilic) contact lenses are indicated for daily wear use for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 1.50 diopters that does not interfere with visual acuity. The lens acts to enhance the apparent color of the eye with a sparkle of glittering colors.

6. **Pre-clinical Testing and Results**

The following *in vitro* tests were performed on GLITTEREYES™ contact lenses for the determination of substantial equivalence in accordance with the May 1994 Premarket Notification (510(k) Guidance Document for Daily Wear Contact Lenses:

- *Ion Exclusion Chromatographic HPLC Analysis of Cell Growth Inhibition (CGI) Extracts*
  - Results: Elution peaks were noted but were considered non-cytotoxic based on toxicology data.
- *Non-volatile Extractables (%NVE)*
  - Results: The mean percent % NVE for GLITTEREYES™ and ILLUSIONS® were substantially equivalent.

- *Compatibility Testing with Lens Care Products*
  - Results: GLITTEREYES™ lenses met color, optical, and physical parameters after thirty cycles with selected lens care regimens. There was no statistical difference in the percent transmittance between baseline and the thirty-cycle measurement.
- *Luminous Percent Transmittance*
  - Results: GLITTEREYES™ met the specifications of EU, ANSI, and ISO standards.
- *Oxygen Permeability*
  - Results: No significant difference in values for oxygen permeability for GLITTYEREYES™ or ILLUSIONS® lenses.
- *Mechanical Analysis*
  - Results: The higher modulus in GLITTEREYES™ was also due to the function of the glitter pigment which makes it a stiffer lens than ILLUSIONS®.
- *Metrology*
  - Results: All lenses measured met specifications for diameter, optical power, optical quality, base curve radius (BCE), and mean center thickness.
- *Leachability Study*
  - Results: Saline extraction of GLITTEREYES™ contact lenses showed no migration of the glitter pigments through the polymeric lens material and is, therefore, non-cytotoxic.
- *L929 Agar Overlay Diffusion Assay*
  - Results: No diffusion of the agar layer was noted for all tested lenses. Lenses are non-cytotoxic.
- *Direct Contact Assay*
  - Results: No reactivity was noted after GLITTEREYES™ lenses were placed in direct contact with the monolayer media. The lenses were found to be non-cytotoxic.
- *USP MEM Elution Assay*
  - Results: No morphological changes, reduction in cell density, or cell lysis was noted when evaluating the extracts. Lenses are non-cytotoxic.
- *L929 Cell Growth Inhibition (CGI) Assay*
  - Results: The L929 cell population inhibition met acceptable criteria limits.

7. **Clinical Summary**

The clinical study of twenty-two subjects was conducted from August 17, 2000 to October 4, 2000 in which the primary objective was to measure wearer satisfaction. Key safety and efficacy variables of this study were biomicroscopy, subjective comfort and vision. Visual acuity and overall fit were also measured. Results of the clinical evaluation demonstrated similar overall performance to the predicate ILLUSIONS® contact lens. No new questions regarding safety or efficacy of the GLITTEREYES™ lenses were noted. Thus, CIBA Vision believes GLITTEREYES™ (tefilcon) soft (hydrophilic) contact lens is substantially equivalent to the currently marketed predicate device, ILLUSIONS®, an is safe and effective when worn on a daily wear basis (less than 24 hours while awake).

8. **Description of Safety and Substantial Equivalence**

GLITTEREYES™ lenses represent a modification to CIBA Vision's ILLUSIONS® (tefilcon) lenses. Both lenses are made of the same contact lens material and in the same manner except for the pigment encapsulated within the center of the lenses. A series of *in vitro* and clinical studies were completed to establish substantial equivalence to currently marketed, predicate device. All testing was conducted in accordance with and in conformance to applicable device regulations. Results demonstrate the GLITTEREYES™ Soft Contact Lens is substantially equivalent to the ILLUSIONS® Soft Contact Lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2000

Ms. Terrina Wilder
Regulatory Affairs Associate
CIBA VISION Corporation
11460 Johns Creek Parkway
Duluth, GA 30097-1556

Re: K003071
Trade Name: Glitter Eyes™ (tefilcon) Soft (hydrophilic) Contact Lenses
Regulatory Class: II
Product Code: 86 LPL
Dated: November 15, 2000
Received: November 17, 2000

Dear Ms. Wilder:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number: *This is a new 510 (k) Notification. (number to be assigned)*

Device Name: **GLITTER EYES™ (tefilcon) Soft (hydrophilic) Contact Lens**

Indications for Use:
GLITTER EYES™ (tefilcon) soft (hydrophilic) contact lenses are indicated for daily wear use for the correction of refractive ametropia (myopia and hyperopia) in not-aphakic persons with non-diseased eyes that may exhibit astigmatism up to 1.50 diopters that does not interfere with visual acuity. The lens acts to enhance the apparent color of the eye with a sparkle of glittering colors.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☒ or Over-the-Counter: ☐

Eric C, PhD
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003071